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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,817	04/21/2004	Latifa Abdennebi-Najar	05032-00054	7701

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EXAMINER

WORLEY, CATHY KINGDON

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/828,817</p>	<p>Applicant(s)</p> <p align="center">ABDENNEBI-NAJAR ET AL.</p>	
	<p>Examiner</p> <p align="center">Cathy K. Worley</p>	<p>Art Unit</p> <p align="center">1638</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9 and 11-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 11-13, as they relate to thyroid stimulating hormone, drawn to a plant comprising a cell comprising a functional mammalian enzyme or functional fragment thereof providing N-glycan biosynthesis additionally having been provided with an expression vector comprising a nucleic acid encoding a thyroid stimulating hormone (TSH) or functional fragment thereof, classified in class 800, subclass 288, for example.
- II. Claims 14-16 and 18-19 and 21, as they relate to TSH, drawn to a plant-derived TSH or functional fragment thereof comprising an extended N-linked glycan at least comprising galactose, the use of said TSH for the production of a pharmaceutical composition, and a pharmaceutical composition comprising said TSH, classified in class 530, subclass 397, for example.
- III. Claims 1-9 and 11-13, as they relate to gonadotrophin-receptor, drawn to a plant comprising a cell comprising a functional mammalian enzyme or functional fragment thereof providing N-glycan biosynthesis additionally having been provided with an expression vector

comprising a nucleic acid encoding a gonadotrophin-receptor or functional fragment thereof, classified in class 800, subclass 288, for example.

- IV. Claims 14-21, as they relate to gonadotrophin-receptor, drawn to a plant-derived gonadotrophin-receptor or functional fragment thereof comprising an extended N-linked glycan at least comprising galactose, the use of said gonadotrophin-receptor for the production of a pharmaceutical composition, and a pharmaceutical composition comprising said gonadotrophin-receptor, classified in class 530, subclass 397, for example.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I and II are patentably distinct. The plant of group I can be made without using the protein or composition of group II, and the protein of group II can be made without using the plant of group I, for example, the protein of group II can be made in CHO cells.

A search for the plant of group I will require searching the literature for molecular farming techniques and bioengineering of plant-derived glycoproteins. A search for the protein and composition of group II will require searching in the literature for extraction and fractionation of proteins wherein the fractions may contain TSH and for use of TSH in pharmaceutical compositions. These searches are not coextensive; therefore examining both inventions would constitute an undue

burden. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The inventions of groups I-II are patentably distinct from the inventions of groups III and IV. The inventions of groups I-II are related to TSH, whereas the inventions of groups III and IV are related to gonadotrophin-receptor. These are different proteins with their own unique amino acid sequence and structure, and therefore, they are patentably distinct.

A search for the plant of group I or the protein and composition of group II would require searching the literature for information about TSH, whereas a search for the plant of group III or protein and composition of group IV would require searching the literature for information about gonadotrophin-receptor. These searches are not coextensive; therefore examining both inventions would constitute an undue burden. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The inventions of groups III and IV are patentably distinct. The plant of group III can be made without using the protein or composition of group IV, and the protein of group IV can be made without using the plant of group III, for example, the protein of group IV can be made in CHO cells.

A search for the plant of group III will require searching the literature for molecular farming techniques and bioengineering of plant-derived glycoproteins and receptors. A search for the protein and composition of group IV will require searching in the literature for extraction and fractionation of proteins wherein the fractions may contain gonadotrophin-receptor and for use of gonadotrophin-receptor in pharmaceutical compositions. These searches are not coextensive; therefore examining both inventions would constitute an undue burden. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A call was made on Dec. 27, 2005 to TaskBritt, P. C. (the attorney's office) to request an oral election to the above restriction requirement, but he/she was unable to answer the phone. A message was left with Betty Vowles indicating that if an election was not made by phone by Friday, Dec. 30, 2005, then the restriction requirement would be sent in the mail. No telephone call was received by the end of the day on Dec. 30, 2005, therefore, the restriction requirement was sent in the mail.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

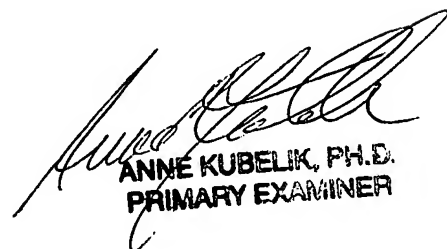
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW
12/27/05



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER